



Attorney's Docket No.: 16614-030001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Thomas E. Tarara et al.
Serial No. : 10/612,393
Filed : July 3, 2003
Title : ENGINEERED PARTICLES AND METHODS OF USE

Art Unit : 1616
Examiner : Sharmila S. Gollamudi

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 09/886,296, filed on June 21, 2001. With the exception of the following references, all references listed on the attached PTO-1449 form were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application:

Foreign Patents:

1.	CA 2036844	Canada	08/23/1991
2.	CA 2136704	Canada	05/28/1995
3.	EP 0655237	Europe	05/31/1995
4.	EP 0391896	Europe	03/02/1994
5.	EP 0493437	Europe	08/02/1995
6.	EP 0513127	Europe	07/19/1995
7.	EP 0539522	Europe	12/30/1998
8.	EP 0553298	Europe	11/17/1994
9.	EP 0556256	Europe	08/30/1995
10.	EP 0587790	Europe	01/03/1996

11/14/2005 CNGUYEN 00000040 10612393

01 FC:1806

180.00 0P

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV 584759176 US

November 9, 2005

Date of Deposit

Applicant : Thomas E. Tarara et al.
Serial No. : 10/612,393
Filed : July 3, 2003
Page : 2 of 2

Attorney's Docket No.: 16614-030001

11.	EP 0588897	Europe	02/28/1996
12.	EP 0605578	Europe	01/10/1996
13.	EP 0656206	Europe	06/07/1995
14.	EP 0658101	Europe	06/21/1995

Non-Patent References

15. Mutterlein, et al., "New technology for generating inhalation aerosols—preliminary results with the piezoelectrical pocket-inhaler", J. Aerosol Med., 1:231 (1988)
16. "Aerosols, Metered-Dose Inhalers, and Dry Powder Inhalers", Pharmacopeial Forum, 22(6): 3065 (1996)

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action or a Notice of Allowance. A check for \$180 in payment of the late submission fee of §1.17(p) is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: November 9, 2005



Jennifer A. Zanocco
Reg. No. 54,563

Fish & Richardson P.C.
500 Arguello Street, Suite 500
Redwood City, California 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

Substitute Form PTO-1449 (Modified) 10/01/00		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant <small>(Use several sheets if necessary)</small>		Applicant Thomas E. Tarara et al.		
		Filing Date July 3, 2003	Group Art Unit 1616	
(17 CFR 1.10(f)(8)(b))				

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
	1	AU 714998	11/19/1997	Australia			
	2	CA 2036844	08/23/1991	Canada			
	3	CA 2136704	05/28/1995	Canada			
	4	EP 0655237	05/31/1995	Europe			
	5	EP 0391896	03/02/1994	Europe			
	6	EP 0493437	08/02/1995	Europe			
	7	EP 0513127	07/19/1995	Europe			
	8	EP 0539522	12/30/1998	Europe			
	9	EP 0553298	11/17/1994	Europe			
	10	EP 0556256	08/30/1995	Europe			
	11	EP 0587790	01/03/1996	Europe			
	12	EP 0588897	02/28/1996	Europe			
	13	EP 0605578	01/10/1996	Europe			
	14	EP 0656206	06/07/1995	Europe			
	15	EP 0658101	06/21/1995	Europe			
	16	JP 03038592	02/19/1991	Japan			

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	17	Ahlneck et al., "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State", Int. J. of Pharmaceuticals, 62:87-95 (1990)
	18	Altenbach et al., "Ca ²⁺ Binding to Phosphatidylcholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formulation of a Ca ²⁺ Complex with Two Phospholipid Molecules" Biochem. 23:3913-3920 (1984)

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.		
		Filing Date July 3, 2003	Group Art Unit 1616	

Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	19	Babincova et al., "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposomes: Possible Implications for Exocytosis", Physiol. Res., 48(4):319-321 (1999)	
	20	Buckton et al., "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders", Int. J. of Pharm., 123:265-271 (1995)	
	21	Buldt et al., "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes", J. Mol. Biol. 123:673-691 (1979)	
	22	Cevc, G., "Membrane Electrostatics" Biochim. Biophys. Acta., 1031(3):311-382 (1990)	
	23	Dellamary et al., "Hollow Porous Particles in Metered Dose Inhalers", Pharm. Research 17(2): 168-174 (2000)	
	24	Duzgunes et al., "Studies on the Mechanism of Membrane Fusion. Role of Head-Group Composition in Calcium- and Magnesium-Induced Fusion of Mixed Phospholipid Vesicles" Biochim. Biophys. Acta., 642:184-195 (1981)	
	25	Ebara et al., "Interactions of Calcium Ions with Phospholipid Membranes" Langmuir, 10:2267-2271 (1994)	
	26	Eisenberg et al., "Absorption of Monovalent Cations to Bilayer Membranes Containing Negative Phospholipids" Biochem., 18(23):5213-5223 (1979)	
	27	Goldbach et al., "Spray-Drying of Liposomes for a Pulmonary Administration I. Chemical Stability of Phospholipids", Drug Develop Inc. Pharm., 19(19):2611-2622 (1993)	
	28	Gordon et al., "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. I. Non-Crystalline Copolymers", J. Appl. Chem., 2:493-500 (1952)	
	29	Hancock et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", J. of Pharm. Sci., 86(1):1-12 (1997)	
	30	Hancock et al., "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solids", Pharm Res., 11(4):471-477 (1994)	
	31	Hauser et al., "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers", Biochim. Biophys. Acta., 813:343-346 (1985)	
	32	Hauser et al., "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" Biochem., 23:34-41 (1984)	

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.		
		Filing Date July 3, 2003	Group Art Unit 1616	

Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	33	Huster et al., "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction", Biophys. J., 77(2):879-887 (1999)	
	34	Huster et al., "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" Biophys. J. 89(6): 3011-3018 (2000)	
	35	Jacobson et al. "Phase Transitions and Phase Separations in Phospholipid Membranes Induced by Changes in Temperature, pH, and Concentration of Bivalent Cations" Biochem. 14(1):152-161 (1975)	
	36	Kwon et al., "Calcium Ion Adsorption on Phospholipid Bilayers-Theoretical Interpretation" J. Jap. Oil Chem Soc. 43(1):23-30 (1994)	
	37	Lis et al., "Adsorption of Divalent Cations to a Variety of Phosphatidylcholine Bilayers", Biochem. 20:1771-1777 (1981)	
	38	Lis et al., "Binding of Divalent Cations to Dipalmitoylphosphatidylcholine and Its Effect on Bilayer Interaction", Biochem. 20:1761-1770 (1981)	
	39	Millqvist-Fureby et al., "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures", Int. J. Pharm. 191:103-114 (1999)	
	40	Millqvist-Fureby et al., "Spray-Drying of Trypsin - Surface Characterization and Activity Preservation", Int. J. Pharm., 188:243-253 (1999)	
	41	Mutterlein, et al., "New technology for generating inhalation aerosols—preliminary results with the piezoelectrical pocket-inhaler", J. Aerosol Med., 1:231 (1988)	
	42	Parasassi et al., "Calcium-Induced Phase Separation in Phospholipid Bilayers. A Fluorescence Anisotropy", Cellular and Molecul. Bio., 32(3):261-266 (1986)	
	43	"Aerosols, Metered-Dose Inhalers, and Dry Powder Inhalers", Pharmacopeial Forum, 22(6): 3065 (1996)	
	44	Reboiras, M.D., "Activity Coefficients of CaCl ₂ in the Presence of Dipalmitoylphosphatidylcholine-Phosphatidylinositol Vesicles in Aqueous Media", Bioelectrochemistry and Bioenergetics, 39:101-108 (1996)	
	45	Roth et al., "Production of Hollow Spheres", Paragonon Press, Vol. 19, No. 7, pp. 939-942 (1998)	
	46	Royall et al., "Characterisation of Mixture Uptake Effects on the Glass Transitional Behaviour of an Amorphous Drug Using Modulate Temperature DSC", Int. J. Pharm., 192:39-46 (1999)	

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.		
		Filing Date July 3, 2003	Group Art Unit 1616	

Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	47	Satoh, Koichi, "Determination of Binding Constants of Ca ²⁺ , Na ⁺ , and Cl ⁻ Ions to Liposomal Membranes of Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis", Biochem. Biophys. Acta 1239:239-248 (1995)	
	48	Seddon, J.M., "Structure of the Inverted Hexagonal (H11) Phase, and Non-Lamellar Phase Transitions of Lipids", Biochem Biophys. Acta., 1031:1-69, in particular pp. 43-44 and 49-50 (1990)	
	49	Seelig, Joachim, "Handbook Met. - Ligand Interact. Biol. Fluids, Bioinorg. Chem., Section, Metal Ion Interaction with Lipids" pp. 698-706 (1995)	
	50	Shah et al., "The Ionic Structure of Sphingomyelin Monolayers", Biochem Biophys. Acta., 135:184-187 (1967)	
	51	Shavvin et al., "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" Biochem Biophys Acta., 946:405-416 (1988)	
	52	Simha et al., "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers", J. Chem. Physics, 37(5):1003-1007 (1962)	
	53	Sugisaki et al., "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice", Bulletin of the Chem. Soc. Of Japan, 41:2591-2599 (1968)	
	54	Tatulian, S.A., "Binding of Alkaline-Earth Metal Cations and Some Anions to Phosphatidylcholine Liposomes", Eur. J. Biochem., 170:413-420 (1987)	
	55	Tatulian, S.A., "Evaluation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration Dependence Surface Potential", J. Colloid Interface Science, 175:131-137 (1995)	
	56	Verstraeten et al., "Effects of A1(3+) and Related Metals on Membrane Phase State and Hydration: Correlation with Lipid Oxidation", Arch. Biochem. Biophys., 375(2):340-346 (2000)	
	57	Whipps et al., "Growth of Calcium Monohydrate at Phospholipid Langmuir Monolayers", J. Cryst. Growth, 192:243-249 (1998)	
	58	Yamaguchi et al., "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" Colloids and Surface B: Biointerfaces, 5:49-55 (1995)	
	59	Zarif et al., "Amphotericin B Cochleates as a Novel Oral Delivery System for the Treatment of Fungal Infections", Proceedings of the International Symp. on Controlled Release Bioactive Materials., pp. 964-965 (1999)	

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	